ATTACHMENT 3

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

IN RE: DA VINCI SURGICAL ROBOT ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	Lead Case No.: 3:21-cv-03825-VC

Expert Report of Dr. Robert D. Howe

OUTSIDE COUNSEL ONLY—SUBJECT TO PROTECTIVE ORDER

January 18, 2023

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permit increased dexterity and freedom of motion but fewer uses as compared to traditional laparoscopic instruments.

17. It is my opinion that Intuitive maintains rigorous design control and risk management processes which illuminate, and allow Intuitive to account for, the various risks or potential failure modes associated with the EndoWrist instruments. Intuitive's comprehensive design control processes allow Intuitive to design instruments so as to support reliable and consistent performance over a prescribed number of uses.

18. It is my opinion that Intuitive's rigorous testing of its EndoWrist instruments adequately reflects the stresses and forces that instruments are subjected to during clinical use and demonstrates that instruments can only be reliably used a limited number of times. Both Intuitive's life testing and actual, clinical results demonstrate that EndoWrist instruments experience significant wear and tear during their prescribed useful life.

19. It is my opinion that although Rebotix, Restore, and SIS refer to the "reset" services as a "repair,"[11] Rebotix simply devised a method that intercepts communication between the robot and the instrument in order to circumvent the usage limits implemented in each EndoWrist instrument, without adequately addressing the effects of wear and tear that accrue during instrument usage.

20. It is my opinion that there are numerous deficiencies in Rebotix's "EndoWrist Service Procedure" (the "Rebotix Process"),[12] which Restore also employed[13]. The steps performed during the Rebotix Process fail to adequately address many of the risks associated

[11] Def.'s Ex. 136, SIS095115-095139, at SIS095120.

[12] *See* REBOTIX162404 (described *infra* § VI).

[13] *See* Restore-00001538

> determine the read slots such that the Interceptor allows a bit masked version of the DS2505 data to pass to host on an un-intercepted read. On an intercepted read the Interceptor ignores the data passed to it by the DS2505 and substitutes the data to the host with its own data . . . Finally the bus controller which handles the bus interactions to the host 1 wire bus also applies a bit wise AND mask to the data from DS2505 to the host using the data in the internal memory of the Interceptor CPLD. This AND masking provides the host with the appearance that it modified the data in the D52505 as the Interceptor stores the writes from the host.[56]

51. Software design specifications for the Interceptor spell out this functionality as well:

> [1] The Interceptor SHALL provide a factory resettable counter to allow REBOTIX to continue to use the EndoWrists once they are repaired . . .
> [4] The Interceptor SHALL allow the host to perform non-volatile writes to the Interceptor Flash Memory . . .
> [7] The Interceptor SHALL prevent the host from writing to the DS2505 . . .
> [10] For non-intercepted accesses, the Interceptor SHALL pass along bit masked data to the host from the DS2505 during a read process . . .
> [11] The Interceptor SHALL intercept/ substitute data when required . . .
> [12] The Interceptor SHALL respond to the Da Vinci Surgical System host in the same manner as the D52505 . . .[57]

V. Intuitive's Design Control, Risk Management, and Testing Processes

A. Intuitive's Design Control and Risk Management Processes

52. Intuitive employs rigorous and in-depth design control and risk management processes. Without thorough design control and risk management, surgical robots could be hazardous to both patients and surgical staff. Potential risks for instruments for the da Vinci surgical robot system include: debris falling into the surgical field or patient, increased risk of electrical arcing/burning to patient tissue, unintuitive motion of the da Vinci surgical system,

[56] *Id.* at REBOTIX101001.

[57] *Id.* at REBOTIX101002-04.

inaccurate or sluggish motions of the EndoWrist instrument, inadequate or restricted ranges of motion, and the EndoWrist instrument failing to be recognized by the da Vinci surgical system.[58] Thus, measures to control risk are necessary throughout the product development and manufacturing process. Intuitive has an extensive system in place to evaluate and manage risk. This system is in accord with standard medical device industry practice.[59]

1. Design Control

53. As described by the FDA, design controls "are an interrelated set of practices and procedures that are incorporated into the design and development process," which result in earlier detection and correction of any "deficiencies in design input requirements, and discrepancies between the proposed designs and requirements."[60]

54. Intuitive describes its design control process as "[a] systematic framework used to demonstrate that the product works and that it meets the needs of the end-user (intended use) while maintaining safety and effectiveness."[61] Design control involves: (i) design verification, which considers and tests the engineering of a product, and (ii) design validation, which considers whether the product meets the needs of the end-user.[62]

55. Within the design control framework, Intuitive's development process involves detailing what a product must do through a Market Requirements Document ("MRD") and

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[58] *See generally* Intuitive-00538913, Intuitive-00538994.

[59] *See generally* Design Control Guidance for Medical Device Manufacturers, US Food and Drug Administration, available at: https://www.fda.gov/media/116573/download.

[60] *Id.* at 1 ("Design controls increase the likelihood that the design transferred to production will translate into a device that is appropriate for its intended use."). This FDA guidance on design control for medical device manufacturers is applicable to new designs as well as modifications to existing device designs. *Id.* at 2.

[61] Intuitive-00477325 at Intuitive-00477331.

[62] Intuitive-00477217 at Intuitive-00477220; *see also* Intuitive-00477325 at Intuitive-00477331-32.

Product Requirements Documents ("PRD").[63] These user and design needs are then implemented through Architectural Requirements Documents ("ARDs"), Functional Requirements Documents ("FRDs"), and lower level functional requirements and specifications.[64]

2. Risk Management

56. Risk management is part of the design process and involves "the systematic application of management policies, procedures, and practices to the tasks of identifying, analyzing, controlling, and monitoring risk."[65] As described more fully below and reflected in Figure 6, Intuitive's risk management processes are integrated into the design control process and continue through the life of a product.[66]

[63] Intuitive-00477217 at Intuitive-00477222; *see also* Intuitive-00477325 at Intuitive-00477358.

[64] Intuitive-00477217 at Intuitive-00477222; *see also* Intuitive-00477325 at Intuitive-00477364.

[65] Design Control Guidance for Medical Device Manufacturers, US Food and Drug Administration, at 5, available at: https://www.fda.gov/media/116573/download.

[66] Intuitive-00477422 at Intuitive-00477424.

Figure 6.[67]

57. The Intuitive risk management process analyzes "risks in design and process, defines requirements to mitigate them, uses design control to trace them to tests, and analyses *[sic]* residual risk." The risk analysis incorporates both a top-down and bottom-up approach.[68]

58. From a top-down perspective, major risk management procedures and the associated documentation include a clinical risk analysis ("CRA") that is formulated early in the product development process. This procedure aims to define potential problems and mitigations

[67] Intuitive-00477422 at Intuitive-00477424.

[68] Intuitive-00477422 at Intuitive-00477424-25.

to guide product definition. The usability risk analysis ("URA") is formulated after the product is defined and considers how it might be used and misused.[69]

59. From a bottom-up perspective, Intuitive's risk management procedures include several failure mode and effects analyses ("FMEA"), including Design FMEA, ("dFMEA"), Process FMEA ("pFMEA"), and Supplier Process FMEA ("spFMEA"). FMEA analysis is performed after the product or its manufacturing process have been designed, and looks at potential failures of components and the overall system.[70] These procedures—and additional risk management documents—are coordinated with the product design process and design control documents, including definition of user needs, design inputs and outputs, and formal design reviews.[71] This process manages overall risk in the marketed products.

60. A dFMEA is the key method for defining specific risks in a medical device design. In Intuitive's dFMEA process, the device is systematically reviewed to determine the ways it could fail and the effects of a failure.[72] Each significant failure mode is assigned scores for the likelihood of occurrence, the severity of the consequences of failure, and the ability to detect the failure.[73] These scores can be combined to provide a measure of the risk priority. Important risks are then mitigated, i.e., changes to the design or the product use are implemented to reduce the risk.[74]

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[69] Intuitive-00477422 at Intuitive-00477425-26.

[70] Intuitive-00477422 at Intuitive-00477424-27.

[71] Intuitive-00477217 at Intuitive-00477220-24; *see also generally* Intuitive-00477325.

[72] *See generally* Intuitive-00477829.

[73] Intuitive-00477422 at Intuitive-00477457. *See generally* Intuitive-00477829.

[74] *See* Intuitive-00477422 at Intuitive-00477454-457; Intuitive-00477829 at Intuitive-00477844-45.

3. Design Verification and Validation

61. As previewed above, a key aspect of the design control and risk management process is design verification. FDA regulations require that medical device manufacturers perform design verification to "confirm that the design output meets the design input requirements."[75] In other words, the design verification process aims to determine whether the performance specifications (design inputs) are met by the new device (design outputs).[76] The Intuitive design verification process is designed in accordance with these protocols. The goal of design verification is to objectively show that the device is built correctly from an engineering standpoint.[77]

62. Design control and risk management also involve design validation. FDA regulations also require that medical device manufacturers "establish and maintain procedures for validating . . . device design," which "ensure[s] that devices conform to defined user needs and intended uses, and . . . include[s] testing of production units under actual or simulated use conditions."[78] The Intuitive design validation process is designed in accordance with these protocols. The goal of design validation is to objectively show that the device meets user needs.[79]

[75] Design Control Guidance for Medical Device Manufacturers, US Food and Drug Administration, at 29, available at: https://www.fda.gov/media/116573/download.

[76] *Id.* at 29-30.

[77] *See* Intuitive-00477325 at Intuitive-00477381.

[78] Design Control Guidance for Medical Device Manufacturers, US Food and Drug Administration, at 33, available at: https://www.fda.gov/media/116573/download.

[79] *See* Intuitive-00477325 at Intuitive-00477381-82.

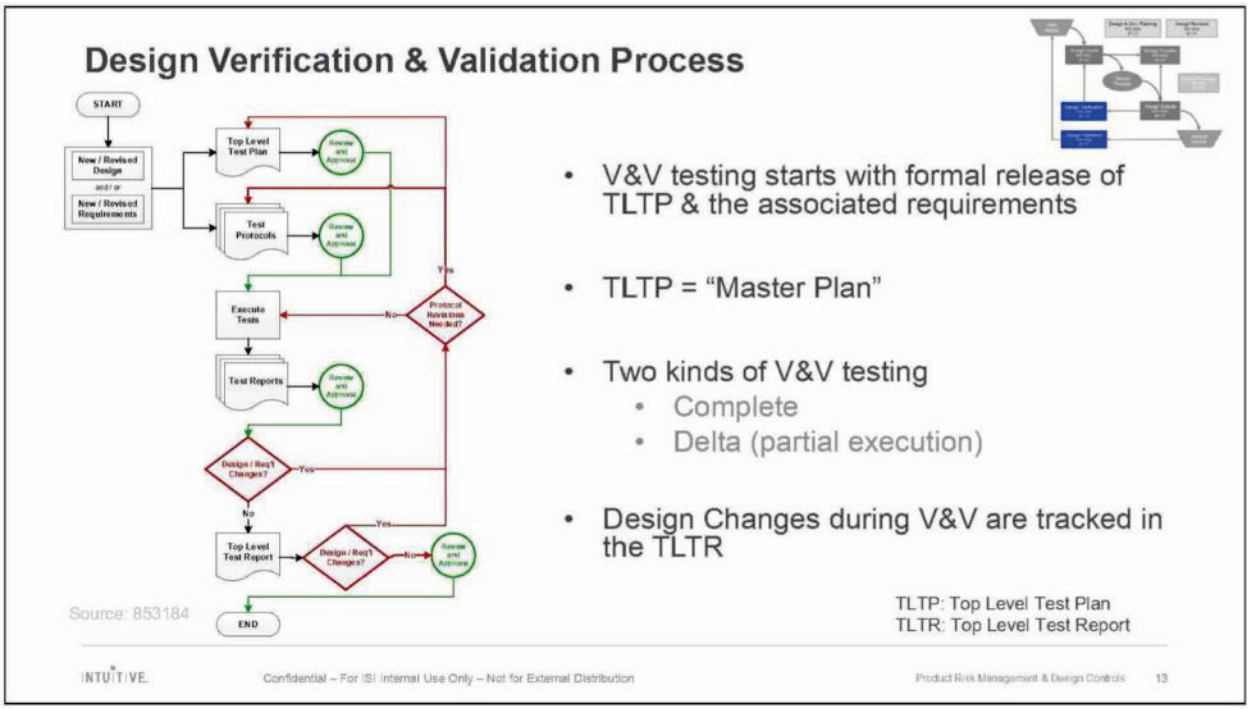

Figure 7.[80]

63. Intuitive has a formal design verification and validation process. *See* Figure 7. Verification and validation testing of a new design or a design change begins with a Top Level Test Plan ("TLTP") that describes the kinds of tests that are to be conducted and the analyses to be performed on the test data, as well as the justification for these tests that relates the specifications to the testing regimen.[81] Test protocols detail the specific steps of each test and the procedure for documenting the testing process and the results. A Top Level Test Report ("TLTR") summarizes the overall verification and validation results.[82] Test reports present the results of the testing as well as analyses and conclusions. Additional documents that specify frequently-conducted test and analysis routines such as standard operating procedures (SOPs)

[80] Intuitive-00477217 at Intuitive-00477229.

[81] Intuitive-00477217 at Intuitive-00477229.

[82] *Id.*

and department operating procedures (DOPs) are used in formulating the test documents, which may be updated as appropriate throughout the verification process.[83] Testing may range from complete tests against specifications for new device designs to more limited "delta" tests for changes to existing designs.[84]

B. Intuitive Designs and Tests Its EndoWrist Instruments to Reliably and Safely Perform Over a Set Number of "Lives"

64. Intuitive's EndoWrist instruments are designed and tested to demonstrate the instruments are safe and effective and meet all of their specified requirements and specifications, including their programmed number of instrument uses, otherwise referred to as instrument "lives."[85]

65. To verify that the design of EndoWrist instruments meets the proposed number of surgical uses, Intuitive conducts life tests.[86] This process is typically documented by a "Protocol for Reliability/Life Testing" and a "Report for Reliability/Life Testing" or similar documents.[87] These test procedures typically include initial cleaning and sterilization cycles then alternating simulated surgical procedures, sometimes also referred to as a simulated surgical use ("SSU"), and cleaning and sterilization cycles, which in combination are referred to as Surgical Use Cases ("SUCs") or life cycles. Attachments to these documents usually include sheets for recording the specific instruments undergoing testing, the equipment used, the observed

[83] *See, e.g.*, Intuitive-00544199 (referencing, among other documents, Intuitive's DOP, Product Verification and Validation (Intuitive-00477154); SOP, Statistical Techniques (Intuitive-00477757); and SOP, Risk Management (Intuitive-00477958)).

[84] Intuitive-00477217 at Intuitive-00477229.

[85] *See generally* Intuitive-00477154.

[86] *See, e.g.*, Intuitive-00544199; Intuitive-00546380; Intuitive-00547846.

[87] *See, e.g.*, Intuitive-00544199; Intuitive-00544494; Intuitive-00546380; Intuitive-00546343; Intuitive-00547846; Intuitive-00546920.

conditions during tests (e.g., sterilization temperatures), checklists for recording each step and the data that results from the tests.[88]

66. A representative example of the Intuitive life testing process is captured in the set of documents describing the life test verification of the IS1200 and IS2000/IS3000 Mega SutureCut needle driver (MSCND) and Large SutureCut needle driver (LSCND).[89] The "Protocol for Reliability/Life Test of MSCND and LSCND Improvements for Grip Cable Life" details the testing process and its justification, as well as the steps required to document the test execution and the results.[90] This protocol describes the goal of the tests in terms of functional requirements (e.g., reliable operation for ten human uses) and the instrument models to which it applies, and uses a worst-case analysis to determine which specific instrument types are most likely to experience failure and thus should be tested.[91]

67. This protocol also uses a statistical Weibull Design of Reliability analysis to determine the number of instrument samples and use cycles that are required to statistically "prove" a number of instrument lives.[92] The analysis applied in connection with the Protocol for Reliability/Life Test of MSCND and LSCND Improvements for Grip Cable Life uses a goal of 90% reliability and 90% confidence ("90/90") for ten human uses.

68. This Protocol for Reliability/Life Test of MSCND and LSCND Improvements for Grip Cable Life is a test following a design change for "updating the proximal clevis pin"

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[88] *See, e.g.*, Intuitive-00544199 (describing attachments and checklists).

[89] *See generally* Intuitive-00544186; Intuitive-00544195; Intuitive-00544197; Intuitive-00544198; Intuitive-00544199; Intuitive-00544388.

[90] *See generally* Intuitive-00544199.

[91] *Id*. at Intuitive-00544200.

[92] *Id*. Weibull Design of Reliability analysis is further detailed in the Intuitive's "Statistical Techniques – Department Operating Procedure," Intuitive-00477757.

that was instituted to "reduce the occurrence of grip cable failures."[93] The tests are designed to confirm that this change to the design maintains the specified level of reliability and confidence, so a relatively small sample size of eight units was tested due to the presence of a similar predicate device.[94] Each of these units is put through a total of 15 "life cycles," which comprise an initial six cleaning and sterilization cycles, followed by fifteen simulated surgical uses and cleaning and sterilization cycles to validate 10 human surgical uses.[95]

69. Simulated surgical procedures for life tests are described in the test report as "developed by the Clinical Development Engineering team." *See* Figure 8. The simulated surgical procedure requires a series of maneuvers of the instrument that replicate how the instrument is used in an applicable laparoscopic surgical operation. *See* Figures 8, 9, 10. In the example of the life testing of the MSCND and LSCND instruments, these steps include wrist circles (moving the instrument tip in a circular pattern), needle throws (driving the needle through a single stitch), suture pulls, tissue lifts, and tissue pushes. *See* Figure 9. Animal tissue models (in this case a beef rib roast) or synthetic models are used to provide reaction forces that emulate the forces produced in surgical procedures. *See* Figure 11. For example, the tissue push maneuver is described as "[p]ush with a force of approximately 2 lbs . . . ."[96] Maneuvers are done in an order that replicates typical surgical usage and repeated a specific number of times that conservatively approximates repetitions in surgery.[97]

[93] Intuitive-00544199 at Intuitive-00544201.

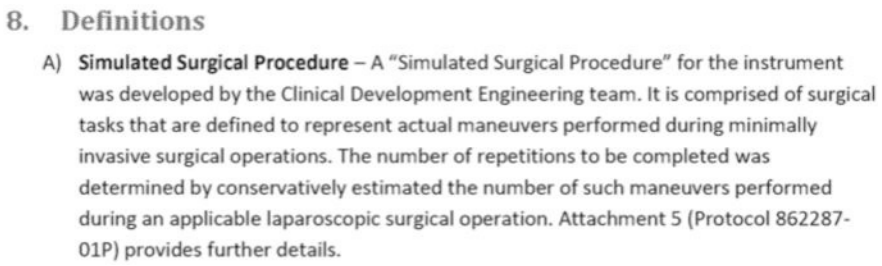
[94] Intuitive-00544494 at Intuitive-00544494.

[95] Intuitive-00544199 at Intuitive-00544200, Intuitive-00544209.

[96] *Id.* at Intuitive-00544201.

[97] *See* Intuitive-00544494 at Intuitive-00544496.

70. By defining a simulated surgical procedure based on observed maneuvers used in applicable laparoscopic surgeries, using animal tissue or synthetic models to emulate forces used in surgical procedures, performing maneuvers in an order replicating typical surgical usage and employing a conservative approximation of the number of maneuvers to be performed during an applicable laparoscopic surgical operation, Intuitive tests instruments in a way that helps ensure the instruments operate reliably and safely over their programmed number of instrument uses.



8. Definitions

A) **Simulated Surgical Procedure** – A "Simulated Surgical Procedure" for the instrument was developed by the Clinical Development Engineering team. It is comprised of surgical tasks that are defined to represent actual maneuvers performed during minimally invasive surgical operations. The number of repetitions to be completed was determined by conservatively estimated the number of such maneuvers performed during an applicable laparoscopic surgical operation. Attachment 5 (Protocol 862287-01P) provides further details.

Figure 8.[98]

[98] Intuitive-00544494 at Intuitive-00544496.

7 Definitions

The following definitions are to describe the specific surgical maneuvers as outlined in section 12.0.

A) **Needle Throw** - Position instrument over the specified model (beef roast or uterine training model as specified in 12.7.1) in a fully wristed position – ~90° pitched or yawed. If possible, all tasks should be performed in this position. A complete throw includes driving the needle into a significant bit of tissue and pulling it completely out using the subject instrument. The assistant instrument can be used to reposition the needle between throws. Note: Uterine training model is more difficult to throw needles through and is thought to better represent the tissue encountered in most gynecological procedures.

B) **Wrist Circle** - Positioning of the instrument can be mimicked by making a looping motion with the grips in the open and closed position. Move the wrist in a circle through its entire range of pitch and yaw motion, forward and reverse.

C) **Suture Pull** - The two ends of the suture are then grasped and pulled apart to simulate tightening a knot. Wrist motion should be used to tighten the knots as much as possible.

D) **Suture Cut** – Secure a length of 0-Silk or 0-Vicryl suture so that it is lightly tensioned using two assistant instruments. Cut using the test instrument.

E) **Tissue Lift** - Grasp the beef roast with instrument. Lift the beef roast using wrist pitch or yaw.

F) **Tissue Push** - Push with a force of approximately 2 lbs using a resistive force such as rubber bands. Move the resistive load several inches. Perform with jaws closed and instrument pitched.

G) **Dips** - A dip is completed when the instrument is dipped into a fluid mixture for 3 seconds. The entire wrist should be submerged and rolled in the fluid during the dip.

H) **Instrument Changes** - Remove instrument from the PSM, then reengage the instrument on the PSM.

Figure 9.[99]

[99] Intuitive-00544199 at Intuitive-00544201.

12 Simulated Surgical Procedure (SSP)

The following table defines a clinical life simulation cycle for the MSCND instrument. This cycle utilizes the motions defined above (see section 7) and arranges/distributes them in a way that more closely approximates the expected usage patterns.

MSCND, One (1) Simulated Life Use

# of executions	Task
1	Dip
10	Needle Throws, Forehand (using Beef Roast)
10	Needle Throws, Backhand (using Beef Roast)
1	Instrument Change
Repeat Above Two Times	
1	Dip
20	Wrist Circle, Grips Closed (but not squeezed)
30	Suture Pulls
1	Instrument Change
Repeat Above Six Times	
1	Dip
10	Tissue Lift, Release
10	Tissue Push, Release.
1	Instrument Change
Repeat Above Three Times	
1	Dip
10	Needle Throws, Forehand (using Beef Roast)
10	Needle Throws, Backhand (using Beef Roast)
1	Instrument Change
Perform Above a Single Time	
30	Suture cuts
Perform Above a Single Time	

Figure 10.[100]

[100] Intuitive-00544199 at Intuitive-00544206.

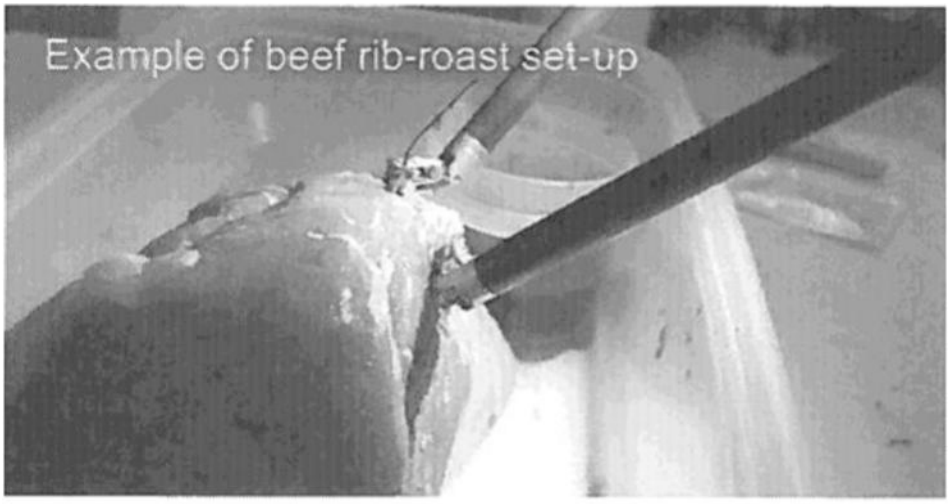


Figure 11.[101]

71. As expected with a rigorous life testing process, failures are observed during life testing of Intuitive EndoWrist instruments. In the MSCND and LSCND example, one of the eight instruments under test suffered a failure on the fourth test cycle, when "the grip close cable derailed from the distal idler pulley during testing."[102] Other examples of life testing that resulted in failures includes:

- Life testing of the 8mm permanent cautery hook, where failures were observed in three of the twelve test instruments during SUC trials 12, 17 and 21.[103]
- Life testing of 8mm monopolar curved scissors, where a derailment failure occurred in SUC trial 6.[104]

[101] Intuitive-00544456 at Intuitive-00544464.

[102] Intuitive-00544494 at Intuitive-00544500; *see also id.* at Intuitive-00544497.

[103] Intuitive-00589150 at Intuitive-00589153.

[104] Intuitive-00546920 at Intuitive-00546920. Instrument intuitive motion also failed for a different instrument in SUC trial 11 and for two additional instruments in SUC trial 12. *See id.*

- Life testing of 8mm monopolar curved scissors where a cable break was observed during SUC trial 7.[105] (Note that Intuitive considers the IS2000/3000 and IS4000 Monopolar Curved Scissors to be equivalent in terms of their distal portions.)[106]

72. As mentioned above, Intuitive has standard procedures for modeling the reliability of the instrument by fitting the life test data to a Weibull reliability model.[107] The Weibull Distribution is "a parameterized continuous probability distribution that is commonly used in failure analysis."[108] Use of the Weibull model provides the ability to predict the reliability of the instrument as a function of number of uses, as well as uncertainty estimates (confidence intervals) for these estimates.[109] This model is also used to establish testing parameters such as sample size.[110] The use of these procedures is important because it accounts for the potential for failures throughout a product's useful life and ensures instruments meet minimum reliability requirements throughout that useful life.[111] The Weibull model is a well-recognized and appropriate method for modeling the reliability of instruments.

C. <u>As EndoWrist Instruments Are Used in a Hospital Setting to Perform Surgical Procedures, They Experience Wear and Tear that Ultimately Leads to Instrument Failure.</u>

73. Gradual degradation of an instrument over time is expected given the design of EndoWrist instruments and it is one of the risks that is identified through Intuitive's risk analyses

[105] Intuitive-00546343 at Intuitive-00546360.

[106] *See e.g.*, Intuitive-00546343. The IS4000 system is commercially known as the da Vinci Xi surgical system.

[107] *See* Intuitive-00477597.

[108] *Id.*

[109] *See* Intuitive-00477597; Intuitive-00477620.

[110] *See* Intuitive-00477620.

[111] Intuitive-00477597 at Intuitive-00477597-98.